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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,816	03/27/2002	Michael Valentine Agrez	SW-046 XX	9944

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WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP  
TEN POST OFFICE SQUARE  
BOSTON, MA 02109

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,816

Applicant(s)

AGREZ ET AL.

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 139, 141, 143-154, 163, 169, 171, 176, 177, 185-201, 217-225, 236-238 and 240-246 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

1. Please note that the examiner assigned to this application has changed.
2. Claims 1-138, 140, 142, 155-162, 164-168, 170, 172-175, 178-184, 202-216, 226-235, 239 are canceled. Claims 240-246 have been added. Claims 139, 141, 143-147, 150-152, 154, 163, 169, 171, 177, 193, , 196, 197, 217-222 and 225 have been amended. Claims 139, 141, 143-154, 163, 169, 171, 176, 177, 185-201, 217-225, 236-238 and 240-246 are pending.
3. After review and reconsideration, the restriction requirement of February 11, 2004 is withdrawn.

### ***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 139, 141, 143-154, 176, 177, 191, 192, 201, drawn to a fusion protein adapted for passing across a cell membrane and incorporating an inhibitor for inhibiting binding of a MAP kinase to an integrin, and an agent for inhibiting binding of a MAP kinase to an integrin comprising a targeting moiety for targeting a cell expressing the integrin; an inhibitor moiety for inhibiting binding of the MAP kinase to the integrin and a facilitator moiety for facilitating passage of the inhibitor moiety across the cell membrane wherein said facilitator moiety is linked to said targeting moiety and an agent identified to be capable of binding to a binding domain of an integrin for a MAP kinase.

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Group 2, claims 163, 169 and 171 comprising an isolated nucleic acid encoding a fusion protein adapted for passing across the outer cell membrane and incorporating an inhibitor moiety for inhibiting the binding of a MAP kinase to an integrin, expression vectors and host cells thereof.

Group 3, claims 185-190, 193-200, drawn to a method for screening for an agent, or isolating an agent capable of inhibiting the binding of a MAP kinase to a binding domain of an integrin

Group 4, claims 217-225, 236-238 and 240-246, drawn to a method of modulating activity of a cell comprising treating said cell with an effective amount of an agent that inhibits binding of the MAP kinase to the binding domain of an integrin for said MAP kinase.

The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims lack unity of invention because they are lacking a special technical feature which links all of the groups.

Claims 192 and 217 are anticipated by Pillinger et al (PNAS, 1998, Vol. 95, pp. 14540-14545) or Gu et al (Journal of Cell biology, 1998, Vol. 143, pp. 1375-1383).

Claim 192 is drawn to an agent identified to be capable of inhibiting binding of a Map kinase to a binding domain of an integrin for the MAP kinase by the method as defined in claim 187. This is a product-by-process claim. The M.P.E.P.(2113 [r-1]) teaches

**PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE  
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE  
IMPLIED BY THE STEPS**

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777

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F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Thus any disclosure of the same product will anticipate the claim.

Claim 217 is drawn to a method of modulating the activity of a cell comprising treating the cell with an effective amount of an agent that inhibits binding of a MAP kinase to the binding domain of an integrin.

Pillinger et al disclose that salicylates inhibit Erk activation and integrin-dependent neutrophil adhesion. Thus, salicylates are the same as the agent claimed irrespective of the process of identification of said agent. The disclosure of inhibiting neutrophil adhesion fulfills the specific embodiment of claim 217 specifying modulation of a cell.

Gu et al disclose PTEN as an agent which inhibits integrin and MAP kinase signaling molecules. Gu et al disclose that integrins stimulate the Ras/Erk/MAP signaling pathway and PTEN reduces Shc phosphorylation and interaction with Grb2 as well as Ras-Erk-MAP kinase pathways for integrin and growth factor signaling that then affects cell spreading and focal contact formation (Figure 8).

Because the claims are not novel over the prior art, they are lacking a special technical feature and restriction for examination purposes is proper.

Groups 1 and 2 are different products having different structures which are made by different methods and have different uses. Groups 3 and 4 have different method objectives, method steps and use different reagents. Group 1 is related to Group 4 as product and process of use. In the instant case the product of group 1 can be used in a process to raise an antibody. Because Groups 1-4 have non-coextensive subject matter, restriction for examination is proper.

Applicant is advised that a complete response to this restriction will include an election, even if the restriction is traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

10/18/2004

  
**KAREN A. CANELLA PH.D**  
**PRIMARY EXAMINER**

Continuation of Disposition of Claims: Claims pending in the application are 139,141,143-154,163,169,171,176,177,185-201,217-225,236-238 and 240-246.